REMARKS

Status of Claims

Claims 69-92, and 94-96 are withdrawn as drawn to non-elected inventions. Claims 55-65, 67, 68, and 93 currently being examined.

Rejections Under 35 USC § 112

The Action rejects claims 55-56, 67, and 68 under 112 first paragraph, as allegedly lacking enablement for the full scope of the claims. Applicants continue to traverse this rejection, as a composition claim that is enabled for at least one utility, as is admitted by the Action, is fully enabled under the 1st paragraph of 112.

Applicants submit that claim 55 is a composition claim, and that the method of making the composition and a method of using the composition are fully enabled as admitted by the Examiner. Nothing more is required. The rejection is based on reading a limitation into the claim that is not there and then requiring that that limitation also be enabled. There is no basis for such a rejection.

1. The claims are enabled under 35 USC §112, first paragraph for a composition of water soluble peptides and there is no legal requirement that the Specification describe and/or enable every possible use for that composition.

The first paragraph of 35 U.S.C. § 112 requires the Specification to enable a person skilled in the art to make and use the claimed invention. The MPEP elaborates on use requirement as it provides, "if a statement of utility in the Specification contains within it a connotation of how to use, and/or the art recognizes that standard modes of administration are known and contemplated, 35 U.S.C. 112 is satisfied." MPEP § 2164.01(c). Further, "if any use is enabled when multiple uses are disclosed, the application is enabling for the invention." *Id.* Thus, when a claim is drawn to a composition, there is no legal requirement that the Specification describe or enable *every* possible use for that composition so long as at least one use is enabled.

A. The Examiner's enablement rejection misconstrues the invention and improperly reads a new limitation into it.

The Examiner's rejection of the claims for lack of enablement is based the erroneous concept that the claimed material must be used only in therapeutic formulations, and further

only in topical therapeutic formulations. *See* Final Office Action dated March 7, 2007, page 3 ("[T]he specification has enabled how to make the peptide composition and how to use it topically to stimulate growth of useful cell types, and has not enabled any uses other than topically for stimulating wound healing and cell growth."). Although the Specification describes therapeutic formulations that may be made with the claimed composition, including topical formulations, the claimed composition is in no way limited to those described formulations. The invention of claim 55 is the powdered peptide composition. The composition is shown in the application to have useful bioactivity. *See* Para. [0021]-[0022]. The Examiner is attempting to read a limitation into the claims based on the described preferred embodiments. The Examiner's position is contrary to the MPEP's statement that "if *any* use is enabled when multiple uses are disclosed, the application is enabling for the invention." MPEP§ 2164.01(c) (emphasis added).

In fact, the Specification discloses many uses for the composition that are known in the art and would not require undue experimentation. The Specification fully enables one of skill in the art to manufacture and use the claimed composition in a formulation for topical administration via a cream, lotion, gel, hydrogel, or wound dressing to a human or animal subject. Para. [0021-0022]. That enablement alone is enough to satisfy the section 112, first paragraph, requirement. But the Specification goes further and provides more uses that are broader than topical application. It says, for example, "the peptide can be used to promote healing, repair, and cell growth in keratinous tissue generally." Para. [0021]. In contrast to the Examiner's assertion that the Specification does not disclose uses other than topical application, the Specification explicitly states that the peptide can be administered orally. Para. [0021] ("[T]he peptide can be applied internally to damaged keratinous tissue lining the GI tract by **orally administering the peptide.**"). The composition could also be used as a nutritional supplement, for example. The Examiner is not only attempting to read a limitation into the claims, she is also imposing a requirement on the Specification that has no basis in the body of patent law. In sum, the application discloses multiple uses for the composition and is enabled as to at least one of those uses, therefore the invention is enabled and satisfies section 112. MPEP § 2164.01(c).

B. Additionally, the Examiner did not meet her burden to show that undue experimentation would be necessary.

The invention is fully enabled because at least one use, as a topical application, is enabled. But even if other uses must also be enabled, the Examiner did not meet her burden to show that undue experimentation would be necessary. "The test of enablement is not whether any experimentation is necessary, but whether, if experimentation is necessary, it is undue." MPEP 2164.01 (citing *In re Angstadt* , 537 F.2d 498, 504, 190 USPQ 214, 219 (CCPA 1976)). The Examiner claimed that the composition is not enabled as to non-topical applications because it would require undue experimentation. *See* Final Office Action dated March 7, 2007, page 4. Tellingly, the Examiner offered no explanation of what experimentation would be required, and why any such experimentation would be "undue," other than to say that trial and error experimentation would be required. *Id.* Clearly, the Examiner did not meet her "burden to establish a reasonable basis to question the enablement provided." MPEP 2164.04. Where no explanation is offered, there is simply no basis for a reasonable explanation.

C. Use as an orally administered peptide is enabled in the Specification because methods of use for orally administered peptides are well known in the art.

Even if experimentation would be required to enable an orally administered peptide, the MPEP provides that "[i]f one skilled in the art, based on knowledge of compounds having similar physiological or biological activity, would be able to discern an appropriate dosage or method of use without undue experimentation, this would be sufficient to satisfy 35 U.S.C. 112, first paragraph." MPEP § 2164.01(c); *In re Wands*, 858 F.2d 731, 735 (Fed. Cir. 1988) ("A patent need not disclose what is well known in the art."). Methods of use for orally administered proteins are well known in the art. It is a well known fact that proteins and peptides are composed of amino acids, and that amino acids have nutritional value. Many protein and amino acid supplements are now commercially available. No or little experimentation is necessary to place the peptides in a gel capsule or compress them into a tablet, for example, to be used as an oral supplement for its known nutritional value. Neither would it require undue experimentation to determine whether such supplementation would have a healing effect on the lining of the gastro-intestinal tract. Thus, the Specification satisfies section 112, first paragraph, because placing proteins in an orally administered form is well known in the art. MPEP § 2164.01(c).

D. The Examiner's reliance on *In re Wands* is misplaced because the criteria in *Wands* are not applicable to the present composition claim.

The Examiner relied on the factual inquiries as applied in *In re Wands,* 858 F.2d 731, 8 USPQ 2d 1400 (Fed Cir. 1988), to reach her conclusion that the claims are not enabled for the full scope of the claims. The criteria in *Wands* are not applicable to the present composition claim. For example, the question in *Wands* was whether the Specification taught one of skill how to make the antibodies that were used in the claimed method of immunoassay to detect hepatitis B surface antigen. *Wands*, 858 F.2d at 733. Nowhere do Appellants find an issue of whether all possible uses of the antibodies were enabled. In addition, in all the various later Federal Circuit cases that have cited *In re Wands*, Appellants cannot find a single one that applies the *Wand* factors to a composition claim to determine whether all possible uses of the composition are enabled by the Specification.

The issue here is not whether the Specification enables all possible uses of the compositions of peptides, but rather, the enablement of the peptide composition independent of adding it to a particular type of carrier. The Specification contains more than adequate description of how to obtain the peptide composition and also teaches how to use the composition to stimulate growth of useful cell types. Nothing more is required for enablement of the composition claims. Appellants submit, therefore, that this rejection is improper and requests that the rejection be overturned.

The Action does not refute this discussion nor offer any authority for the continued rejection of the claims under this statute.

Applicant requests once again that this rejection be withdrawn.

Rejections Under 35 USC 102

The Action also rejects claims 55-65, 67, 68 and 93 are rejected as anticipated by US 5,276,138.

A. The scope and content of the '138 reference do not in any way include or suggest all the elements of the present claims.

The Examiner rejected claims 55-65, 67, 68, and 93 as anticipated by 5,276,138 ('138) because, according to the Examiner, the "'138 patent teaches a solubilized keratin powder from animal hair or wool" and teaches the steps "oxidation by hydrogen perioxide or peracetic acid; filtration, neutralization, precipitation of a powder; and washing the filtrate with solvent such as acetone, methanol or ethanol." Final Office Action dated March 7, 2007, page 6. Appellants respectfully traverse the rejection because the present invention is based on the surprising result

that the *filtrate* of oxidized hair contains biologically active peptides that can be collected by neutralizing the filtrate and precipitating out the peptides with a water-miscible organic solvent. Para. [0009]. The '138 patent teaches discarding the *filtrate* of oxidized hair and using the *precipitate* to recover much larger molecular weight proteins. Col. 4, lines 29-33; Example 1 at Col. 5-6 . Thus, the '138 patent contains no description or suggestion of the present invention.

B. The '138 reference describes a different process for obtaining the peptides.

'138 teaches a process by oxidizing the hair, filtering it through a mesh (discarding the filtrate), precipitating with an acetic acid, filtering through a filter paper (discarding the filtrate), washing, drying, and pulverizing to obtain a powder. *See e.g.,* ('138) Example 1 at Col. 5-6. The present disclosure, on the other hand, teaches a different process; oxidizing the hair, filtering it (retaining the filtrate to collect the low molecular weight, water-soluble peptides), neutralizing the filtrate with a base, precipitating out the water-soluble peptides by mixing with a water-miscible organic solvent, filtering again and evaporating the precipitate. Para. [0014]-[0018]. Thus, the '138 reference teaches one skilled in the art to discard the objects of the present composition claims by disposing of the filtrate in the first filtration step. The '138 process contains no description of the water-soluble peptides found in the filtrate of the oxidized hair. The present disclosure is not obvious in light of the '138 reference because that reference does not teach or describe the surprising result that the filtrate of oxidized hair contains biologically useful peptides, which are the compositions claimed in the present disclosure.

C. The '138 reference describes different proteins.

The '138 patent describes a composition containing high molecular weight, acid precipitable proteins. This subset of hair proteins is an acidic portion of the oxidized hair that is insoluble at low pH, and thus precipitates in acid. This protein subset has a much higher molecular weight than the peptides precipitated by ethanol at neutral pH as described in the present Specification (Para. [0018]) and claims. The present Specification discloses peptides of an average weight of 850 Daltons. Para. [0020]. In contrast, the '138 reference describes much larger peptides, the majority of which have a molecular weight of 25,000 to 67,000 Daltons. *See* ('138) Fig. 1. Even if the peptides of the present claims were contained within the composition with the larger peptides of the '138 preparation, there is no way to know that from reading the patent. There is also no suggestion in the patent that there is a low molecular weight fraction that

could be isolated, or that any fraction of this preparation would have the cell growth activity of the claimed compositions.

D. Neither does the '138 reference render any claim obvious as it teaches away from the present claims.

The '138 reference does not suggest that any useful fraction of peptides can be precipitated from a soluble preparation (*i.e.,* isolated from the filtrate) of oxidized hair. The '138 does teach that a fraction can be precipitated by lowering the pH of the solution to below 4:

As previously stated, the present invention relates also to the process for recovering the solubilized product of the animal hairs which comprises admixing the solution of said product with an organic acid or an aqueous solution thereof to precipitate said product.

* * *

> Under normal conditions, the pH of the mixed system of the solution of the solubilized product of the animal hairs and the organic acid may be adjusted less than about 4.5, preferably 1-4. **If the pH of the mixed system is more than 4.5, the solubilized product of the animal hairs becomes hard to precipitate.** ('138) Col. 4, lines 29-33, 58-63 (emphasis added).

Thus, the '138 reference also teaches away from t he present claims by teaching that the composition cannot be precipitated at pH above 4.5, and yet the claimed peptides are precipitated at neutral pH. Para. [0009]. Thus the claims are clearly distinguished from the disclosure of '138, both in the process of obtaining them and in their molecular weight, not just because of the process step alone, but because the different chemical characteristics of the two peptide compositions cause them to precipitate under different conditions.

Although the '138 patent discusses the use of a polar solvent such as alcohols, acetone and the like, this step is used to further purify the high molecular weight proteins that was the result of a previous acid precipitation and to "remove trace amounts of stinking components of low molecular weight, colored substances and the like contained in the solubilized product solution of the animal hairs," (Col. 5, line 24) and not to isolate a bioactive subfraction of peptides. The '138 can thus in no way be said to teach or suggest the present claims, and teaches away from the present claims by teaching precipitation from aqueous solution at low pH, and by teaching that only trace amounts of useless contaminants can be removed from the high molecular weight protein preparation by washing with aqueous solution of organic acids and/or

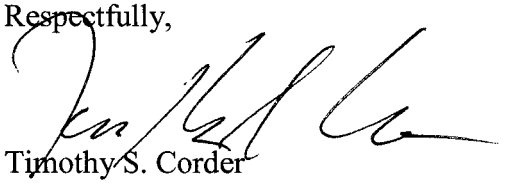
volatile organic solvents. Therefore, the low molecular weight peptides does not meet the description the '138 disclosure.

Applicant requests that all rejections over the '138 patent be withdrawn.

Conclusion

It is Applicant's belief that this is a complete response and that all pending claims are in condition for allowance. Such favorable action is respectfully requested. If the Examiner has any questions or suggestions to more quickly progress the pending claims to issue, a telephone call to the undersigned at 512.542.8446 is welcomed.

Respectfully,



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